EORTC
European Organisation for Research and Treatment of Cancer

ACT EU workshop on ICH E6 R3

Consenting patients

Disclosure

- Voting Member of EMA Management Board
- Co- Chair of the EMA Cancer Medicines Forum
- Co – Chair of the EMA ACT EU Multistakeholder Advisory Group

Disclaimer

Any views expressed in this presentation are mine and should not be understood or quoted as being made on behalf of or reflecting the position of ICH, the ICH E6 Expert Working Group, European Medicines Agency, or one of its committees/working parties or other organisation. They should also not be understood as an official interpretation of the ICH E6 guideline, but are intended to stimulate thoughts and discussion on the topics.

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A few statements

- Patients in clinical trials do evolve in real life
- They represent a sample which can be heavily selected or not (I will focus on the latter)
- Institutions participating to clinical research raise their overall standards and data quality
- New forms of clinical research have emerged
- Simplified clinical trials despite more complex designs are needed to ensure quality by design and decreased burden on sites and patients

This should be reflected in the informed consent documents and processes

How can ICH E6 R3 support more patient-oriented administration of clinical trials?

Reaching to patients in academic settings

- Trend to approach RW: specific focus on pragmatic practice-changing clinical trials
- Patients evolve in real life: integration of clinical trial in routine clinical care
- Trials in clinical settings: RWD, pragmatic elements
- Enabled by technical advances and interactive communication solutions
- Clinical trials should reach patients where they are (communities): improving accessibility (Inequality)and convenience are priorities but also understandability

FDA guidance for integrating RCTs in routine clinical practice

This should be reflected in the informed consent documents and processes

How can ICH E6 R3 support more patient oriented administration of clinical trials?

Selected changes for trials in clinical settings (I)

- Volume of information: the simpler the trial, the simpler the consent

Conundrum 1: keep consent accessible when trial designs become more complex

Conundrum 2: keep protocols simple when trial designs become more complex

Consider: What is the marginal difference and risks between standard and investigation?: consider limiting the informed consent, only to the additional risks as opposed to the expected risks by the treatment in std practice.

Making the Ethical Oversight of All Clinical Trials Fit for Purpose: JAMA. 2025;333(1):75-80. doi:10.1001/jama.2024.0269

Selected changes for trials in clinical settings (II)

- Volume / sequence of information given to the patients:

  For trials with 2 steps for example registration and randomisation later: (immediate versus delayed enrolment)

  TwiCs, or de-escalation: consider giving the information when needed, not all at start.

  Simpler approaches for more complex design, but reflecting real life, along side the evolution of the disease

Additional selected changes.

- Consent withdrawal: treatment or trial? data still to be collected, also in the best interest of the patient for long term toxicity monitoring, outcome follow up
- Amendment: proportionality of medical and ethical relevance on the need to re-consent or not.

Terminology matters (annex II)

- The dichotomy between pragmatic elements and RWD
- Vast majority of data collected during clinical trials, explanatory or pragmatic trials, are part of the routine, so are those pragmatic elements or RWD?
- In addition to pragmatic elements and RWD, the decentralised elements are added as a 3rd dimension: dichotomise between the forms and the methods to collect data versus data resources and their qualification
- Consider approaching the situation from the trial level (rather than the data level) and adapt proportionality : Drug development trials vs public health trials; explanatory vs pragmatic trials. Data they collect will be of different sources and nature (at least in part) but the overall QC/QA processes should be proportional, enforcing the principles of GCP for all trials of course.

Could potentially simplify the concept of data collection during trial and beyond consent.